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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/808,184	03/24/2004	Raghavan Rajagopalan	073979-00030/D1	4580

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EXAMINER	
PACKARD, BENJAMIN J	

ART UNIT	PAPER NUMBER
1612	

MAIL DATE	DELIVERY MODE
06/23/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/808,184	RAJAGOPALAN ET AL.	
	Examiner	Art Unit	
	Benjamin Packard	1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 March 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *11-27* is/are pending in the application.

4a) Of the above claim(s) *13-20* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *11,12 and 21-27* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *11pgs (6/25/2004)*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Information Disclosure Statement

The information disclosure statement (IDS) submitted on 6/25/2004 was previously marked unconsidered due to a software/computer issue and the Examiner apologizes for the confusion. Accordingly, the information disclosure statement is now being considered by the Examiner.

Claim Rejections - 35 USC § 112

Claims 11, 12, and 21-27 were rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement.

This rejection is maintained.

Examiner rejected the claims on the basis that the specification did not support the written description requirement where the term "bombesin receptor binding molecule" is part of the elected compound. Further, there is no evidence that "receptor binding molecules" will attach to a methene group.

Applicants argue the specification teaches the function of the Epitope (E), such that it recognizes and binds to the target surface. Additionally, Applicants submit a declaration and argue that by attaching a bromide to the base chain, a biolomolecule will then react at the peptide -SH or –NH2 to for a bond.

First, the list of "bombesin receptor binding molecule" discussed in the Applicant's arguments filed 3/14/2008 finds no support in the specification. The description requirement of the patent statute requires a description of an invention, not

an indication of a result that one might achieve if one made that invention. See, e.g. In re Wilder, *22 USPQ* 369, 372-3 (Fed. Cir.1984). (Holding that a claim was not adequately described because the specification did "little more than outline goals appellants hope the claimed invention achieve and the problems the invention will hopefully ameliorate.')

Mere indistinct terms (such as various "receptor binding molecules" used herein), however may not suffice to meet the written description requirement. This is particularly true when a compound is claimed in purely functional terms. See Univ. of Rochester v. G.D. Searle, 69 USPQ2d 1886, 1892 (CAFC 2004), stating:

> The appearance of mere indistinct words in a specification or a claim, even an original claim, does not necessarily satisfy that requirement. A description of an anti-inflammatory steroid, i.e., a steroid (a generic structural term) described even in terms of its functioning of lessening inflammation of tissues fails to distinguish any steroid from others having the same activity or function. A description of what a material does, rather than of what it is, usually does not suffice.... The disclosure must allow one skilled in the art to visualize or recognize the identity of the subject matter purportedly described. (Emphasis added).

A description of a chemical genus will usually comprise a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus. See University of California v. Eli Lilly and Co., 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). This is analogous to enablement of a genus under section 112, P 1, by showing the enablement of a representative number of species within the genus.

A chemical genus can be adequately described if the disclosure presents a sufficient number of representative species that encompass the genus. If the genus has substantial variance, the disclosure must describe a sufficient number of species to reflect the variation within that genus. See MPEP 2163. Although the MPEP does not specifically define what constitutes a representative number of species, the courts have

indicated what does not constitute the same. See, e.g.., In re Gostelli, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989), holding that the disclosure of two chemical compounds within a subgenus did not adequately describe such subgenus.

The MPEP lists factors that can be used to determine if sufficient evidence of possession has been furnished in the disclosure of the Application. These include the level of skill and knowledge in the art, partial structure, physical and/or chemical properties, functional characteristics alone or coupled with a known or disclosed correlation between structure and function, and the method of making the claimed invention. Disclosure of any combination of such identifying characteristics that distinguish the claimed invention from other materials and would lead one of skill in the art to the conclusion that the applicant was in possession of the claimed species is sufficient. MPEP 2163.

Here, the claims are directed to a compound where E is selected from various receptor binding molecules. There is no structural information provided in the specification to teach what structure is required to meet the stated function. It appears from the drawing that two possible receptor binders are shown. There may be more incorporated by reference, but that results in a very limited number of receptor binding molecules which do not share common structures which would allow one of ordinary skill to understand the term receptor binding molecule. As such, one of ordinary skill in the art would not understand the structural requirements based only on the general binding functionality language.

Further, it is unclear that the receptor binding molecule must have a peptide chain. In that case, the declaration does not overcome the ability to bind a receptor binding molecule which does not have a peptide backbone.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 11 is rejected under 35 U.S.C. 102(b) as being anticipated by Pinney et al (Biochemistry, Vol 30, No 9 1991, pp 2421-2431).

Pinney et al discloses the use of aryl azides as potent antiestrogens, such as LY117018 and LY139481 (page 2422, 2nd full paragraph and images at the top right corner). The attachment is at the estrogen receptor (page 2422 first few lines). Note, the instant compound may be attached through L as –(CH2)a-, where a can be 0 and X is –(CH2)h- where h is 0.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary

Claims 11, 12, and 21-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sykes et al (US 6,313,274) in view of Pinney et al (Biochemistry, Vol 30, No 9 1991, pp 2421-2431).

Sykes et al teaches phototherapeutic treatment using the protein somatostatin (claim 5). Proffered administration is via injection (column 15 lines 44-64). Sykes also teach the use of arylazides as photoactivatable agents (column 2lines 46-58).

Sykes et al does not teach the attachment of aryl azides as a part of phototherapy.

Pinney et al teaches the addition of an aryl azide enhances the reactivity of the nitrene generated upon photolysis when using receptor binding molecules. Pinney et al further teaches 30 nM fully saturate the ER sites (pg 2426 last paragraph).

Pinney et al does not teach the use protein somatostatin as the receptor binding molecule.

It would have been obvious to one of ordinary skill in the art to recognize that when practicing the method of the primary reference, that the addition of an aryl azide as taught by the secondary reference will improve the performance of the method. Therefore, the combination would be an obvious improvement of the therapy taught in the primary reference.

Conclusion

No claims allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Benjamin Packard whose telephone number is 571-270-3440. The examiner can normally be reached on M-F 8-3:45 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick Krass can be reached on 571-272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Benjamin Packard/
Patent Examiner, Art Unit 1612

/Frederick Krass/

Supervisory Patent Examiner, Art Unit 1612